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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,501	04/15/2004	Reid W. Von Borstel	1331-436	6568

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EXAMINER	
LEWIS, PATRICK T	
ART UNIT	**PAPER NUMBER**
1623	
MAIL DATE	**DELIVERY MODE**
07/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,501	VON BORSTEL ET AL.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04152004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the structures on pages 15-24 are illegible. The amended specification must not contain new matter. The amended specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the amended specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Appropriate correction is required.

Information Disclosure Statement

2. The information disclosure statement filed April 15, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the

application file, but the information referred to therein has not been considered. US Application No. 09/494,242 does not contain copies of the instantly cited documents.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 56-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,020,320. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The examined claims are either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is

recited in claims 1-12 of US 6,020,320. That is, claims 1-12 of US 6,020,320 fall entirely within the scope of claims 56-63 or, in other words, claims 56-63 are anticipated by claims 1-12 of US 6,020,320.

The '320 patent is silent as to treatment or prevention of radiation- or sunlight-induced cellular damage; however, artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. In construing process claims and references, it is the identity of manipulative operations which leads to finding of anticipation. In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. The '320 patent teaches the administration of the instant compounds to an animal. Prevention of radiation- or sunlight-induced cellular damage is not an active methodological step in the process but is rather a consequence of the administration of the deoxyribonucleoside.

5. Claims 56-63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,743,782. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The examined claims are either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is recited in claims 1-8 of US 6,743,782. That is, claims 1-8 of US 6,743,782 fall entirely

within the scope of claims 56-63 or, in other words, claims 56-63 are anticipated by claims 1-8 of US 6,743,782.

The '782 patent is silent as to treatment or prevention of radiation- or sunlight-induced cellular damage; however, artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. In construing process claims and references, it is the identity of manipulative operations which leads to finding of anticipation. In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. The '782 patent teaches the administration of the instant compounds to an animal. Prevention of radiation- or sunlight-induced cellular damage is not an active methodological step in the process but is rather a consequence of the administration of the deoxyribonucleoside.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 56-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

1. the breadth of the claims;
2. the nature of the invention;
3. the state of the prior art;
4. the level of one of ordinary skill in the art;
5. the level of predictability in the art;
6. the amount of direction provided by the inventor;
7. the existence of working examples; and
8. the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 56-63 are drawn to a method for treating or preventing radiation-induced cellular damage or sunlight-induced cellular damage, comprising administering to an animal an effective amount of a composition comprising an acyl derivative of a 2'-deoxyribonucleoside.

The term "radiation-induced cellular damage or sunlight-induced cellular damage" is indefinite but is seen to embrace suntans, sunburns and skin cancer. A sunburn is a burn to living tissue such as skin produced by overexposure to ultraviolet (UV) radiation, commonly from the sun's rays. Exposure of the skin to lesser amounts of UV will often produce a suntan. Usual mild symptoms in humans and animals are

red or reddish skin that is hot to the touch, general fatigue, and mild dizziness. Sunburn can be life-threatening and is a leading cause of skin cancer. Sunburn can easily be prevented through the use of sunscreen, clothing (and hats), and by limiting solar exposure, especially during the middle of the day. The only cure for skin burn is slow healing, although skin creams can help.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974). A broad claim requires a correlatively broad and sufficient disclosure to support it. There is nothing inherently wrong with defining some part of an invention in functional terms; however, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. Examples and description should be of sufficient scope as to justify the scope of the claims. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

The working examples in the specification are limited to the synthesis of the various acyl derivatives of a 2'-deoxyribonucleosides. "Examples of Clinical Administration" have been noted; however, these examples do not demonstrate the treatment or prevention of radiation- or sunlight-induced damage. Furthermore, the instant claims embrace the treatment of a very broad array on conditions including

various skin cancers. The treatment of these conditions is difficult and unpredictable. Melasma is an irregular brown or grayish-brown facial hypermeloanosis, often affecting women, especially those living in areas of intense UV radiation. Gupta et al. J. Am. Acad. Dermatol. (2006), Vol. 55, pages 1048-1065 (Gupta) teaches, "Because of its refractory and recurrent nature, melasma is often difficult to treat."

The instant specification also teaches that the delivery of the instant deoxyribonucleosides is difficult. Pages 2-3 of the specification teaches, "A number of investigators have attempted to use DNA and/or deoxyribonucleosides to treat a variety of conditions in experimental animals and to enhance or augment cellular repair processes, including DNA repair. It has been demonstrated that administration of exogenous DNA to experimental animals after exposure to ionizing radiation can result in dramatically increased survival and functional recovery. Studies on cell cultures in vitro demonstrate that the actual restorative agents are probably deoxyribonucleosides, the enzymatic degradation products of DNA. These compounds enhance the actual repair of damaged DNA in vitro. However, depolymerized DNA or deoxyribonucleosides administered to animals were ineffective in promoting survival or recovery after irradiation. Kanazir et al., Bull. Inst. Nuc. Sci "Boris, Kidrinch" 9:145-153 (1959). There is reason to believe that this apparent contradiction is due to the rapid catabolism of deoxyribonucleosides in vivo by the liver and other organs. Thus, after administration of deoxyribonucleosides, tissues were only exposed to effective concentrations for a matter of minutes."

Undue experimentation is required to determine which deoxyribonucleosides are effective for preventing or treating the specific conditions claimed and the amount of therapeutic agent required for prevention or treatment. There has not been provided adequate guidance in the written description for accomplishing such, as none of the instant deoxyribonucleosides were assessed. Without guidance further guidance, undue trial and error experimentation would be required to screen through the myriad of different chemical molecules to determine those with the desired pharmacological activity.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 56-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are drawn to 2'-deoxyribonucleosides; however, the recited structures are not 2'-deoxyribonucleosides. A deoxyribonucleoside is comprised of two parts: a nitrogenous base and a deoxyribose sugar. The nitrogenous base is always bonded to the 1' carbon of the deoxyribose, which is distinguished from ribose by the presence of a proton on the 2' carbon rather than an -OH group.

The attachment of atoms to the 5'-oxygen is unclear in the recited structures.

Variable R_3 is not part of the recited structures.

The term "effective amount" is indefinite as one of ordinary skill in the art would not be apprised of the actual amount of deoxyribonucleoside to administer. As taught

by the specification, nucleic acids are rapidly degraded by the body. Pages 2-3 teaches, "There is reason to believe that this apparent contradiction is due to the rapid catabolism of deoxyribonucleosides in vivo by the liver and other organs. Thus, after administration of deoxyribonucleosides, tissues were only exposed to effective concentrations for a matter of minutes."

The term "radiation-induced cellular damage or sunlight-induced cellular damage" has not been defined by the specification. One of ordinary skill in the art would not have been apprised by the metes and bounds of the conditions treated or prevented.

In claim 63, the variable M is not defined; structures of formulae (III) and (IV) are unclear. The single and double bonds are not clearly distinguishable.

Conclusion

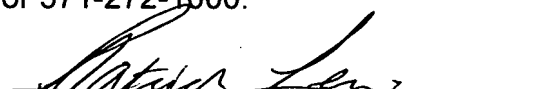
10. Claims 56-63 are pending. Claims 56-63 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Dr. Patrick T. Lewis
Primary Examiner
Art Unit 1623

ptl